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The Copley Consulting Group

Benefits of ERP in an FDA-Regulated Environment: A Practical Guide

This guide will examine why medical device manufacturers are increasingly turning to ERP systems to mitigate compliance risk and turn developmental concepts into commercialized product offerings with greater efficiency.

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The burden of record keeping in FDA-regulated and other highly regulated industries can be considerable. The maintenance of manual records for what are described as GMP relevant data (Good Manufacturing Practice, as established by GAMP 5) is time-consuming and costly to execute, review, approve, store, and maintain.

That's why today's innovative medical device manufacturers are adopting enterprise resource planning (ERP) solutions to reduce this burden. By leveraging data accumulated through business, production, and quality transactions, businesses are able to manage regulatory obligations while streamlining manufacturing processes and improving customer service.

This guide will examine why medical device manufacturers are increasingly turning to ERP systems to mitigate compliance risk and turn developmental concepts into commercialized product offerings with greater efficiency.

Why Adopt an ERP System in an FDA-Regulated Environment?

Using an ERP system to manage multiple business functions allows medical device manufacturers to maintain higher visibility at every stage of the business process, creating practical, real-world benefits – and tangible ROI.

- **Improved compliance:** For medical device manufacturers, it can be a struggle to maintain compliance to strict FDA regulations. Leading ERP systems help organizations establish measures throughout the medical device manufacturing life-cycle, from procurement to sales and distribution, while adhering to strict, evolving and unpredictable local and global regulations.

- **Cloud-based access:** As the medical device industry globalizes, legacy ERP (non-web–enabled) and/or paper-based systems limit the ability of international teams and stakeholders to maintain access to important documentation. Authorized users of cloud-accessible ERP systems can access information whenever they need to, no matter their location.

- **Audit trail:** When an audit is coming up, files must be pulled for review, which in a paper-based system, can be a labor-intensive exercise. In an ERP environment, search functionality makes file retrieval an efficient operation, and simplified reporting provides the auditor with all the necessary details.

- **Automation**: Medical device manufacturers can streamline processes and manage the risk of costly delays by automating areas that typically require error-prone manual interventions. Advanced ERP solutions offer built-in automation capabilities in areas of billing, manufacturing execution systems, and vendor management, among others.

- **Traceability:** Advanced ERP solutions include automated eSignature based lot and serial tracking and traceability to enable swift recall processes and comprehensive audit trails. Modern ERP software for medical device manufacturing companies also support problem diagnosis and corrective and comprehensive audit trails. Modern ERP software for medical device manufacturing companies also support problem diagnosis.

ERP System Requirements for FDA-Regulated Companies

An ERP system deployed in an FDA-validated environment must contain key capabilities required for compliance to 21 CFR §820.70(i) and 21 CFR Part 11 as a minimum. This includes:

- Ability to provide system-wide audit trails.
- Extensive features, controls, and verification of users and what they can access, read, change, and transact.
- Cradle-to-grave traceability leveraging lot and serial controls.
- Electronic signatures with tamperproof reporting and auditing.
- Device master and history record capability.

In addition, the FDA has issued definitive guidelines for medical devices that are computer software controlled. Therefore, for companies that are designing and manufacturing medical devices, it is essential to include a formal testing regimen that meets the level of rigor outlined in the General Principles of Software Validation; Final Guidance for Industry and FDA Staff. These requirements also extend to software that is used to record and maintain device history and quality records, which may include an ERP system.

The methodology used for FDA validation is critical to its acceptability and ability to withstand audit. Because software validation requires a combination of procedural, administrative, and technical controls, no software package can claim to be "validated" or compliant" out of the box. However, leading ERP systems offer a validation support kit, which include test cases and best practice templates to get you started on your validation process as well as project kick-start services to deliver an easy, quick, and proven approach to validation.

Reaping the Benefits of ERP: What to Expect

FDA-regulated businesses are used to the need for detailed work instructions and standard operation procedures as required by their quality management system and current regulatory obligations.

Consequently, they tend to be more knowledgeable and intentional in their choices, have appropriate expectations, and are better able, through documentation, to effectively deploy an ERP solution. The result is a more conscious and effective average deployment.

In addition to strengthening compliance efforts, medical device manufacturers who have adopted ERP system often experience positive outcomes in the following areas:

- **Supply chain management**: With the ability to integrate their entire supply chain internally, from purchasing to manufacturing and distribution, and to link up to the supply chain management systems of distributors and hospitals, medical device manufacturers are able to leverage their ERP system to lower costs and reduce lead times.

- **Quality management**: An ERP system enables medical device manufacturers to establish, track, and manage every engineering activity and supply chain expectation, while supporting business growth and profitability goals. This is accomplished by creating critical manufacturing specifications for products, processes, equipment, and measuring devices, and improving enterprise team collaboration with vendors, customers, and employees.

- **Manufacturing control**: ERP systems make it easier to coordinate complex manufacturing processes, making procedures more reliable and operations more profitable.

- **Sales and operations planning**: By connecting data inputs from various departments and sources, ERP systems equip manufacturing leaders to make data-driven decisions using up-to-date information from throughout their organization.

- **After-market service and maintenance**: A well-designed ERP system helps manufacturers support customers, from installation and ongoing maintenance to break-fix repairs and warranties. Specialized functionality facilitates better management of service calls, warranties, service contracts, scheduled and dispatch of technicians and as-serviced configuration tracking.

ERP for Medical Device Manufacturers: FAQ Expect

How can companies currently utilizing paper-based systems and processes benefit from an ERP system?

Until recently, medical device manufacturers dealt strictly with paper-based documentation. FDA regulations for paper-based documentation are well-established and straightforward, and for companies who have yet to make the shift to electronic forms of document management, reluctance may stem from the cost and effort involving in mapping current SOPs to a new system.

However, it is no secret that paper-based documentation can weaken a manufacturer's ability to ensure compliance throughout a device's lifecycle. Keeping track of physical folders, ensuring wet signatures on critical documents and scouring piles of paper for missing data is time-intensive and error-prone, making data tracking and analysis virtually impossible. Altogether, these issues make for not only a costly and labor-intensive documentation process, but also one that bears additional risk.

ERP systems offer many solutions to common documentation frustrations, but implementing and validating a company-wide ERP system requires commitment and dedication by the company. That's why many companies choose to evolve and refine ERP use over time, by first phasing in transactions most important to FDA recordkeeping.

For example, labor charging, integrated training and certification, and detailed quality records are sometimes challenging to deploy at the level required for FDA recordkeeping based on company culture or available data. In these instances, elements of the current paper-based system of record are maintained to facilitate a low-risk migration, and ERP system validation instead focuses on record auditing, user control and access, and core GMP transactions such as customer and order entry, shipping, inventory management, and purchasing. Additional functionality can then be tackled through a second wave of deployment following system validation.

What are some common barriers to ERP for smaller organizations?

There is a common misconception that ERP systems can only benefit large-scale organizations due to expense, implementation complexity, maintenance costs and a need for internal IT resources. While an ERP system does require a significant investment, not all deployments need have the same scope or price tag.

Small medical device manufacturers should consider what they need from an ERP system, and work with a vendor who can spec out a system to meet their exact requirements. This might include a phased rollout approach, a dedicated consultant for support, training, and change management throughout deployment, and a lean software package designed with the smaller organization in mind.

About The Copley Consulting Group

For 30 years The Copley Consulting Group has delivered Infor CloudSuite™ Industrial ERP implementation success to hundreds of enterprises. From Fortune 1000 companies to start-up operations, Copley provides education, training and technical services melded with a focus on Best Practices. As Infor's micro-vertical practice leader for the FDA Regulated Industry, we have helped dozens of North America's leading medical device and biotech firms achieve software regulatory compliance, while providing business system functionality to meet every client's go-to-market and growth objectives. Copley blends the unique requirements of this stringently regulated industry with a deployment methodology that is client resource sensitive, methodical in execution and honed to reduce project budget and regulatory risk.

For more information about our Infor CloudSuite Industrial (SyteLine) system implementations in FDA regulated environments, contact a Copley Consultant at 855.884.5305 or sales@copleycg.com.

Contact

The Copley Consulting Group
400 Trade Center, Suite 3950
Woburn, MA 01801
855.884.5305
info@copleycg.com

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